

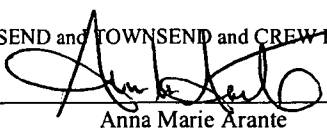
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PATENT  
Attorney Docket No.: 016930-000816US  
Client Reference No.: CJ01656KQ

On March 30, 2007

TOWNSEND and TOWNSEND and CREW LLP

  
Anna Marie Arante

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Heidrun Engler et al.

Application No.: 10/055,863

Filed: January 22, 2002

For: COMPOSITIONS AND METHODS  
FOR ENHANCING DELIVERY OF  
THERAPEUTIC AGENTS TO CELLS

Group Director: 1623

Confirmation No.: 4929

Examiner: Elli Peselev

Art Unit: 1623

SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT UNDER 37  
CFR §1.97 and §1.98

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The references cited on the attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. Copies of the references marked "AV-AX, AZ-BH, BJ- BQ, BS, BU, BV, BX-BZ" [in compliance with the requirements of 37 CFR §1.98(a)(2)] are enclosed. In accordance with 37 CFR §1.98(d), copies of the following references can be found as noted in the following table:

Cited Reference	Application No./Filing Date Patent No/Issue Date:	Attorney Docket No.
AY, BI, BR, BT, BW	08/584,077/January 8, 1996 5,789,244/August 4, 1998	016930-000800US

It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR §1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicant believes that no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,



Frank J. Mycroft  
Reg. No. 46,946

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Substitute for form 1449B/PTO

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

1

of

4

**Complete if Known**

Application Number	10/055,863
Filing Date	January 22, 2002
First Named Inventor	Engler, Heidrun
Art Unit	1623
Examiner Name	Elli Peselev
Attorney Docket Number	016930-000816US

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	2001/0006946 A1	07-05-2001	Engler et al.	
	AB	2002/0111502 A1	08-15-2002	Engler et al.	
	AC	2005/0085427 A1	07-21-2005	Connor et al.	
	AD	US-4,414,150	11-08-1983	Goeddel	
	AE	US-4,456,748	06-26-1984	Goeddel	
	AF	US-4,678,751	07-07-1987	Goeddel	
	AG	US-4,695,623	09-22-1987	Stabinsky	
	AH	US-4,897,471	01-30-1990	Stabinsky	
	AI	US-5,118,512	09-30-1994	O'Leary et al.	
	AJ	US-5,120,316	06-09-1992	Morales et al.	
	AK	US-5,298,222	03-29-1994	O'Leary et al.	
	AL	US-5,532,220	07-02-1996	Lee et al.	
	AM	US-5,602,023	02-11-1997	Csatary, Laszio K.	
	AN	US-5,789,244	08-04-1998	Heidrun Engler et al.	
	AO	US-5,831,062	11-03-1998	Taylor et al.	
	AP	US-5,837,520	11-17-1998	Shabram et al.	
	AQ	US-5,912,236 A	06-15-1999	Xu et al.	
	AR	US-5,923,210	08-03-1999	Gregory et al.	
	AS	US-6,030,956	02-29-2000	Boulikas	
	AT	US-6,066,624	05-23-2000	Woo et al.	
	AU	US-6,207,454	03-27-2001	Zsebo et al.	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
/E.P./	AV	WO	91/18927	A1	12-12-1991	Schering Corporation		<input type="checkbox"/>
	AW	WO	93/00052	A1	01-07-1993	The Regents of the University of Michigan		<input type="checkbox"/>
/E.P./	AX	WO	04/108898	A2	12-16-2004	Canji Inc.		<input type="checkbox"/>

Examiner  
Signature

/Elli Peselev/

Date  
Considered

04/17/2007

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
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				Filing Date	January 22, 2002
				First Named Inventor	Engler, Heidrun
				Art Unit	1623
				Examiner Name	Elli Peselev
Sheet	2	of	4	Attorney Docket Number	016930-000816US

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>		
/E.P./	AY	ADDISON, C. et al., "Intratumoral injection of an adenovirus expressing interleukin 2 induces regression and immunity in a murine breast cancer model" <u>Proc. Natl. Acad. Sci. USA</u> , Vol. 92, pp. 8522-8526 (1995)	<input type="checkbox"/>		
/E.P./	AZ	BENEDICT, W. et al., "Intravesical Ad-IFN $\alpha$ causes marked regression of human bladder cancer growing orthotopically in nude mice and overcome resistance to IFN- $\alpha$ protein" <u>Mol. Ther.</u> , Vol. 10(3): pp. 525-532 (2004)	<input type="checkbox"/>		
/E.P./	BA	FULTS et al., "Sustained-release of urease from a poloxamer gel matrix" <u>J. Parenter. Sci. Technol.</u> 44(2):279-286	<input type="checkbox"/>		
/E.P./	BB	HORTON, H. et al., "Antitumor effects of interferon- $\alpha$ : <i>in vivo</i> therapy of human tumor xenografts in nude mice" <u>Cancer Res.</u> , Vol. 59: pp. 4064-4068 (1999)	<input type="checkbox"/>		
/E.P./	BC	IZAWA, J. et al., "Inhibition of tumorigenicity and metastasis of human bladder cancer growing in athymic mice by <i>interferon-<math>\beta</math></i> gene therapy results partially from various antiangiogenic effects including endothelial cell apoptosis" <u>Clin. Cancer Res.</u> , Vol. 8(4): pp. 1258-1270 (2002)	<input type="checkbox"/>		
/E.P./	BD	JOHNSTON et al., "Insulin disposition following intramuscular administration of an insulin/poloxamer gel matrix" <u>J. Parenteral Science and Technology</u> 43(6):279-286.	<input type="checkbox"/>		
/E.P./	BE	JOHNSTON et al., "Sustained delivery of interleukin-2 from a poloxamer 407gel matrix following intraperitoneal injection in mice" <u>Pharmaceutical Research</u> 9(3):425-434 (1992)	<input type="checkbox"/>		
/E.P./	BF	KOSHIDA, K. et al., "Prospects for molecular research in urological oncology: bladder cancer" <u>Hinyokika kiyo. Acta Urologica Japonica</u> , Vol. 47(1): pp. 815-818 (2001), abstract only	<input type="checkbox"/>		
/E.P./	BG	KUBALL, J. et al., "Successful adenovirus-mediated wild-type <i>p53</i> gene transfer in patients with bladder cancer by intravesical vector instillation" <u>J. Clin. Onc.</u> , Vol. 20(4): pp. 957-965 (2002)	<input type="checkbox"/>		
/E.P./	BH	LIN, L.F. et al., "A system for the enhancement of adenovirus mediated gene transfer to uro-epithelium" <u>J. Urol.</u> , Vol. 168: pp. 813-818 (2002)	<input type="checkbox"/>		
/E.P./	BI	LU, B. et al., "Topical application of viral vectors for epidermal gene transfer" <u>J. Invest. Dermatol.</u> , Vol. 108, No. 5; pp. 8903-808 (1997) (Abstract Only)	<input type="checkbox"/>		
/E.P./	BJ	LUO, Y. et al., "Recombinant bacilli calmette-guérin (BCG) expressing human interferon-alpha 2B demonstrates enhanced immunogenicity," <u>Clin. Exp. Immunol.</u> 2001, Vo. 123, pp. 264-270.	<input type="checkbox"/>		
Examiner Signature	/Elli Peselev/			Date Considered	04/17/2007

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
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				Filing Date	January 22, 2002
				First Named Inventor	Engler, Heidrun
				Art Unit	1623
				Examiner Name	Elli Peselev
Sheet	3	of	4	Attorney Docket Number	016930-000816US

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
/E.P./	BK	Material Safety Sheet, Pluronic F127 NF (Poloxamer NF), BASF Corporation Chemicals Division, Parsoppany, NJ	<input type="checkbox"/>	
/E.P./	BL	MAZUR, B. and W. PACIORKIEWICZ, "Studies on the effect of some disinfectants on virus activity" <u>Med. Dosw. Mikrobiol.</u> ; Vol. 26, No. 4; pp. 331-337 (1974)	<input type="checkbox"/>	
/E.P./	BM	OSIFCHIN et al., "Identification of a p53 binding site in the human retinoblastoma susceptibility gene promoter" <u>J. Biol. Chem.</u> 269(9):6383-6389 (1994)	<input type="checkbox"/>	
/E.P./	BN	PEC et al., "Biological activity of urease formulated in poloxamer 407 after intraperitoneal injection in the rat" <u>J. Pharmacological Sciences</u> 81(7):626-630 (1992)	<input type="checkbox"/>	
/E.P./	BO	SHIAU, A.L. et al., "Postoperative immuno-gene therapy of murine bladder tumor by <i>in vivo</i> administration of retroviruses expressing mouse interferon- $\gamma$ " <u>Cancer Gene Therapy</u> , Vol. 8(1): pp. 73-81 (2001)	<input type="checkbox"/>	
/E.P./	BP	SIMONS et al., "Antisense-c-myc oligonucleotides inhibit intimal arterial smooth muscle cell accumulation <i>in vivo</i> " <u>Nature</u> 359:67-69 (1992)	<input type="checkbox"/>	
/E.P./	BQ	SMITH et al., "Adenovirus mediated expression of therapeutic plasma levels of human factor IX in mice" <u>Nature Genetics</u> 5:397-402 (1993)	<input type="checkbox"/>	
/E.P./	BR	STREULI, M. et al., "At least three human type $\alpha$ interferons: Structure of $\alpha 2$ " <u>Science</u> , Vol. 209, pp. 1343-1347 (1980)	<input type="checkbox"/>	
/E.P./	BS	SUTTON, M. et al., " <i>In vivo</i> adenovirus-mediated suicide gene therapy of orthotopic bladder cancer" <u>Mol. Ther.</u> , Vol. 2(3): pp. 211-217 (2000)	<input type="checkbox"/>	
/E.P./	BT	TOLOZA, E.M. et al., " <i>In vivo</i> cancer gene therapy with a recombinant interleukin-2 adenovirus vector" <u>Cancer Gene Therapy</u> , Vol. 3, No. 1, pp. 11-17 (1996)	<input type="checkbox"/>	
/E.P./	BU	TRAPNELL, <u>Adv. Drug Del. Rev.</u> 12:185-199 (1993)	<input type="checkbox"/>	
/E.P./	BV	TYLER, R and G.A.J. AYLIFFE, "A surface test for virucidal activity of disinfectants: preliminary study with herpes virus" <u>J. Hosp. Infect.</u> Vol.9, No. 1; pp. 22-29 (1987)	<input type="checkbox"/>	
Examiner Signature	/Elli Peselev/		Date Considered	04/17/2007

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/E.P./	BW	XU, X. et al., "Adenovirus-mediated interferon- $\gamma$ transfer inhibits growth of transplanted HTLV-1 tax tumors in mice" <u>Human Gene Therapy</u> , Vol. 7, pp. 471-477 (1996)	<input type="checkbox"/>	
/E.P./	BX	YEI et al., "In vivo evaluation of the safety of adenovirus-mediated transfer of the human cystic fibrosis transmembrane conductance regulator cDNA to the lung" <u>Human Gene Therapy</u> 5:731-744 (1994)	<input type="checkbox"/>	
/E.P./	BY	ZHANG, J-F. et al., "Treatment of a human breast cancer xenograft with an adenovirus vector containing an interferon gene results in rapid regression due to viral oncolysis and gene therapy" <u>Proc. Nat'l. Acad. Sci. USA</u> , Vol. 93, pp. 4513-4518 (1996)	<input type="checkbox"/>	
/E.P./	BZ	ZHOU et al., "Visualizing superficial human bladder cancer cell growth in vivo by green fluorescent protein expression" <u>Cancer Gene Therapy</u> , Vol. 9; pp. 681-686 (2002)	<input type="checkbox"/>	

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